



MEDICAL DEVICES DEVELOPMENT

ARE YOU IN THE PROCESS OF DEVELOPING A MEDICAL DEVICE OR AN IVD?

Since the 2017 New Regulation announcement, manufacturers have up until 2020 to prepare and get their products ready and compliant. Venn provide the knowledge and support to organisations developing medical in vitro, traditional and software devices. Under the New EU Medical Device Regulations, staying competitive and keeping up to date requires a proactive response. Medical Device and Diagnostics companies must consider regulatory compliance, patient safety/risk assessment, data integrity and adequate monitoring for all the products. Here's how we can help!

HOW WE CAN SUPPORT YOU

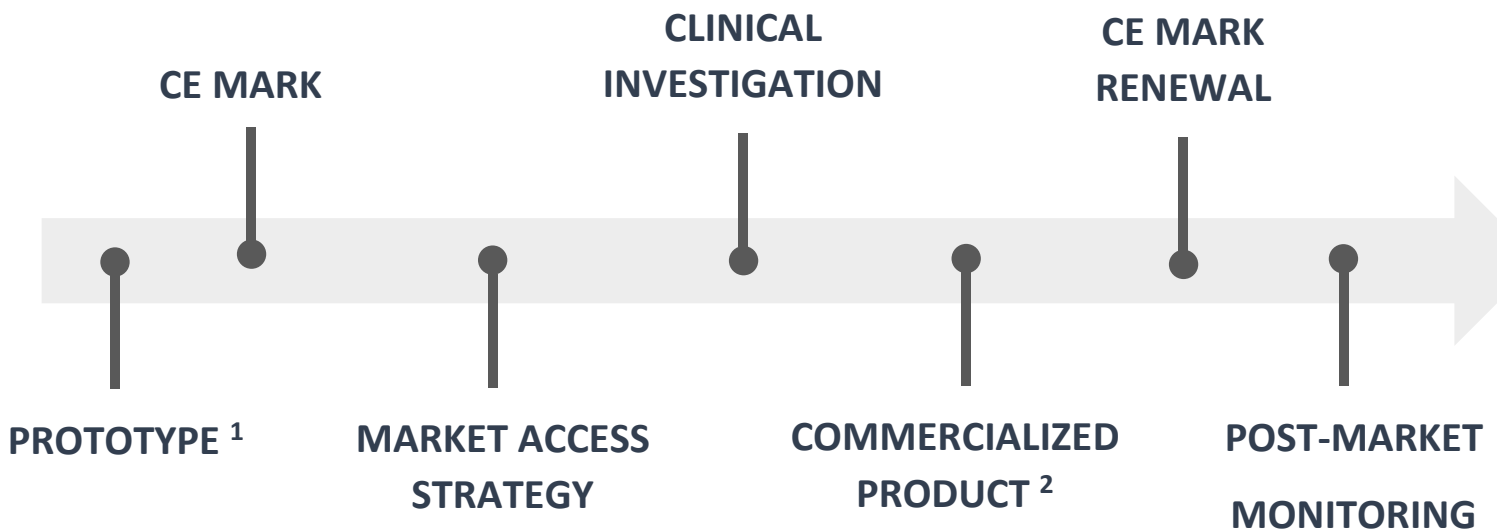
- Regulatory Strategy and Consultancy
- Definition of Intended Use of Device
- Classification
- Conformity Assessment
- CE Marking
- Market Access – EU Reimbursement
- Reimbursement Strategies
- Study Design
- Clinical Investigation Planning and Execution
- Monitoring
- Biometry

CUSTOMER TESTIMONIAL

“Venn Life Sciences are like an extension of our company. They partnered with us to provide the expertise we needed at a critical time, managed the project under our direction, and helped us get our critical research journey underway.”

Paul Bilars L.L.M. MSc. – CEO, VarmX

WHERE ARE YOU ON THE JOURNEY?



Successful development and commercialisation of Medical Device and In-Vitro Diagnostics in compliance with the MDR and IVDR regulations requires planning and support. Our team of experts can guide customers throughout the product lifecycle whether they are developing or enhancing products by providing the adapted services.

If you are starting to develop a Medical Device or an In-Vitro Diagnostic, Venn Life Sciences propose a specific package (1) to support you all along this journey. We also offer a specific package for companies that need to renew their certification (2). Please contact us for more information: getintouch@vennlife.com

1 MD EARLY PHASE PACKAGE

2 POST-MARKET PACKAGE

VENN LIFE SCIENCES IN SUMMARY

Venn Life Sciences is an Integrated Health Product Development partner offering a unique combination of drug and device development expertise and clinical trial design and management. This enables us to create, plan and execute drug and medical device development programs effectively and seamlessly for our clients.

We have 30 years of experience in drug and medical device development and we have a strong European footprint.

